

# EXHIBIT 12

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:  
Bair Hugger Forced Air Warming  
Products Liability Litigation

## This Document Relates To:

## All Actions

MDL No.

15-2666 (JNE/FLM)

**VIDEOTAPED DEPOSITION**

OF

CHRISTOPHER NACHTSHEIM

## Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:

Amy L. Larson, RPR

Job No. 113495

Page 2

1 NACHTSHEIM  
 2 APPEARANCES:  
 3 ON BEHALF OF 3M:  
 4 CHRISTIN GARCIA, ESQUIRE  
 5 FAEGRE BAKER DANIELS  
 6 2200 Wells Fargo Center  
 7 90 South Seventh Street  
 8 Minneapolis, MN 55402  
 9  
 10 DEBORAH LEWIS, ESQUIRE  
 11 BLACKWELL BURKE  
 12 431 South Seventh Street  
 13 Minneapolis, MN 55415  
 14  
 15 FOR THE PLAINTIFF:  
 16  
 17 MICHAEL SACCHET, ESQUIRE  
 18 CIRESI CONLIN  
 19 225 South Sixth Street  
 20 Minneapolis, MN 55402  
 21  
 22 ALSO PRESENT: Kraig Hildahl, Videographer  
 23  
 24  
 25

Page 3

1 NACHTSHEIM  
 2 INDEX:  
 3 EXAMINATION BY: PAGE  
 4 Ms. Garcia.....8, 372  
 5 Mr. Sacchet.....254  
 6 EXHIBITS MARKED FOR IDENTIFICATION:  
 7 Exhibit 1.....10  
 8 Acknowledgment and Agreement to be Bound  
 9 No Bates  
 10 Exhibit 2.....10  
 11 Notice of Videotaped Deposition of  
 12 Christopher Nachtsheim  
 13 No Bates  
 14 Exhibit 3.....12  
 15 Christopher Nachtsheim, Ph.D.,  
 16 Curriculum Vitae  
 17 No Bates  
 18 Exhibit 4.....15  
 19 Forced-Air warming and ultra-clean  
 20 ventilation do not mix  
 21 No Bates  
 22 Exhibit 5.....15  
 23 Patient Warming Excess Heat:  
 24 The Effects on Orthopedic Operating  
 25 Room Ventilation Performance  
 26 No Bates  
 27  
 28 Exhibit 6.....29  
 29 Statistical Analysis for HPS Protocol 003  
 30 Bates Albrecht\_0016008 - Albrecht\_0016012  
 31  
 32 Exhibit 7.....34  
 33 Research Agreement  
 34 Bates Belani\_000054 - Belani\_000061  
 35  
 36 Exhibit 8.....37  
 37 Logistic Regression -  
 38 Mark Albrecht - March 11, 2016  
 39 Bates Albrecht\_0002275 - Albrecht\_0002278

Page 4

Page 5

1 NACHTSHEIM  
 2 INDEX: (Cont'd.)  
 3 EXHIBITS MARKED FOR IDENTIFICATION: PAGE  
 4 Exhibit 9.....38  
 5 11/1/2013 E-mail Chain  
 6 Subject: Re: Analytically speaking  
 7 Bates Albrecht\_0000101 - Albrecht\_0000102  
 8  
 9 Exhibit 10.....53  
 10 3/24/10 E-mail Chain  
 11 Subject: First Publication I'd Like to  
 12 Include you on  
 13 Bates Nachtsheim\_0000364 - Nachtsheim\_0000382  
 14  
 15 Exhibit 11.....58  
 16 April 2010 E-mail Chain  
 17 Subject: Testing  
 18 Bates Nachtsheim\_0001408 - Nachtsheim\_0001410  
 19 Exhibit 12.....62  
 20 4/8/10 E-mail  
 21 Subject: Update on testing  
 22 Bates Nachtsheim\_0001571  
 23  
 24 Exhibit 13.....78  
 25 4/9/10 E-mail  
 26 Subject: Problem with laminar flow lab  
 27 Bates Nachtsheim\_0000832 - Nachtsheim\_0000833  
 28 Exhibit 14.....84  
 29 April 2010 E-mail Chain  
 30 Subject: Update  
 31 Bates Nachtsheim\_0001545 - Nachtsheim\_0001547  
 32  
 33 Exhibit 15.....95  
 34 May 2010 E-mail Chain  
 35 Subject: Abstract "crud and bug"  
 36 !!Important!!  
 37 Bates Nachtsheim\_0000118 - Nachtsheim\_0000120  
 38  
 39 Exhibit 16.....100  
 40 5/29/10 E-mail  
 41 Subject: Both abstracts,  
 42 Statistical files and data files  
 43 Bates Nachtsheim\_0000191 - Nachtsheim\_0000192,  
 44 Nachtsheim\_0000211 - Nachtsheim\_0000223

1 NACHTSHEIM  
 2 INDEX:  
 3 EXHIBITS MARKED FOR IDENTIFICATION: PAGE  
 4 Exhibit 17.....114  
 5 July 2010 E-mail Chain  
 6 Subject: Manuscript drafts for meeting  
 7 Bates Nachtsheim\_0000548 - Nachtsheim\_0000549,  
 8 Nachtsheim\_0000556 - Nachtsheim\_0000576,  
 9 Nachtsheim\_0000600 - Nachtsheim\_0000608,  
 10 Nachtsheim\_0000577 - Nachtsheim\_0000599,  
 11 Nachtsheim\_0000613 - Nachtsheim\_0000615  
 12  
 13 Exhibit 18.....146  
 14 7/8/10 E-mail  
 15 Subject: Arizant FDA Warning Ltr  
 16 Bates Nachtsheim\_00000385  
 17 Exhibit 19.....188  
 18 1/4/11 E-mail Chain  
 19 Subject: Article I was talking about  
 20 Bates Nachtsheim\_0000177 - Nachtsheim\_0000179  
 21  
 22 Exhibit 20.....192  
 23 December 2010/January 2011 E-mail Chain  
 24 Subject: Rough Copy  
 25 Bates Nachtsheim\_0001110 - Nachtsheim\_0001115,  
 26 Nachtsheim\_000127 - Nachtsheim\_000130,  
 27 Nachtsheim\_0001199 - Nachtsheim\_0001201,  
 28 Nachtsheim\_0001206  
 29  
 30 Exhibit 21.....195  
 31 Forced Air Warming versus Conductive  
 32 Fabric Warming - An Evaluation of  
 33 Laminar Operating Room Ventilation Disruption  
 34 Bates Nachtsheim\_0001206 - Nachtsheim\_0001229  
 35  
 36 Exhibit 22.....205  
 37 Implementing Effective SSI Surveillance  
 38 No Bates  
 39  
 40 Exhibit 23.....226  
 41 1/25/11 E-mail Chain  
 42 Subject: Minor Changes and a Query  
 43 Bates Nachtsheim\_0000750 - Nachtsheim\_0000751,  
 44 Nachtsheim\_0000727 - Nachtsheim\_0000749

Page 6

1                   NACHTSHEIM  
 2 INDEX: (Cont'd.)  
 3 EXHIBITS MARKED FOR IDENTIFICATION: PAGE  
 4 Exhibit 24.....231  
 January 2011 E-mail Chain  
 Subject: Papers you are involved in  
 Bates Nachtsheim\_0000819 - Nachtsheim\_0000821  
 6  
 Exhibit 25.....277  
 April 2015 E-mail Chain  
 Subject: Statistical Practitioners Forum:  
 Advanced DOE Class  
 Bates 3MBH01293497 - 3MBH01293499  
 9  
 Exhibit 26.....322  
 Doctor Says a Device He Invented  
 Poses Risks  
 11 No Bates  
 12 Exhibit 27.....333  
 Table  
 13 Bates Albrecht\_0002298  
 14 Exhibit 28.....341  
 Would Complications Following Rivaroxaban  
 15 Administration - A Multi-Centre Comparison  
 with Low Molecular Weight Heparin for  
 Thromboprophylaxis in Lower Limb  
 Arthroplasty  
 17 Bates Nachtsheim\_0000451 - Nachtsheim\_0000466  
 18 Exhibit 29.....369  
 Forced-Air Warming Does Not Worsen Air  
 19 Quality in Laminar Flow Operating Rooms  
 Bates 3MBH00985628 - 3MBH00985633  
 20  
 Exhibit 30.....377  
 Curriculum Vitae  
 21  
 22  
 23  
 24  
 25

Page 8

1                   NACHTSHEIM  
 2 TSG Reporting.  
 3         Will counsel please introduce  
 4 themselves for the record.  
 5         MS. GARCIA: Christin Garcia,  
 6 counsel for defendants 3M and Arizant.  
 7         MS. LEWIS: Deborah Lewis also  
 8 counsel for defendants 3M and Arizant.  
 9         MR. SACCHET: Michael Sacchet for  
 10 plaintiffs.  
 11         THE VIDEOGRAPHER: Will the court  
 12 reporter please swear in the witness and then  
 13 we can proceed.  
 14  
 15         CHRISTOPHER NACHTSHEIM,  
 16 a witness in the above-entitled action,  
 17 after having been first duly sworn, was  
 18 deposed and says as follows:  
 19  
 20                   EXAMINATION  
 21 BY MS. GARCIA:  
 22 Q. Hello, Professor Nachtsheim.  
 23 A. Hello.  
 24 Q. Thank you for coming here today. Could you  
 25 start by, for the record, just providing your

Page 7

1                   NACHTSHEIM  
 2 THE VIDEOTAPED DEPOSITION OF CHRISTOPHER  
 3 NACHTSHEIM, taken on this 29th day of November,  
 4 2016, at the Law Offices of Faegre Baker  
 5 Daniels, LLP, 2200 Wells Fargo Center, 90 South  
 6 Seventh Street, Minneapolis, Minnesota, commencing  
 7 at approximately 9:11 a.m.  
 8  
 9                   P R O C E E D I N G S  
 10  
 11         THE VIDEOGRAPHER: This is the  
 12 Start of tape labeled number 1 of the  
 13 videotaped deposition of Christopher  
 14 Nachtsheim in the matter of In Re: Bair  
 15 Hugger Forced Air Warming Products Liability  
 16 Litigation in the U.S. District Court for the  
 17 District of Minnesota, Case Number 15-2666  
 18 (JNE/FLM).  
 19         This deposition is being held at the  
 20 Faegre Baker law firm in Minneapolis,  
 21 Minnesota, on November 29th, 2016. We are  
 22 going on the record at 9:11 a.m. My name is  
 23 Kraig Hildahl, I'm the legal video specialist  
 24 from TSG Reporting. The court reporter is  
 25 Amy Larson also in association with

Page 9

1                   NACHTSHEIM  
 2 full name and spell your last name and let us  
 3 know your address.  
 4 A. Christopher John Nachtsheim. And it's N as  
 5 in north, A-C-H-T, S as in Sam, H-E-I-M.  
 6 Address is 1789 Summit Avenue, St. Paul,  
 7 Minnesota 55105.  
 8 Q. Thank you. Have you ever been deposed  
 9 before?  
 10 A. Yes.  
 11 Q. Okay. The one rule of deposition I just want  
 12 to reinforce today is if you have any  
 13 difficulty understanding -- well, if you  
 14 don't understand my question, if you would  
 15 like me to clarify something, will you please  
 16 let me know that?  
 17 A. Uh-huh. Yes.  
 18 Q. Yes?  
 19 A. Yes.  
 20 Q. There's rule number 2.  
 21 A. That's rule number 2, I knew that.  
 22 Q. You will need to say things out loud so that  
 23 we can get an accurate transcription of the  
 24 record in writing where your head movements  
 25 can't be taken down, and then we will try not

Page 322

1                   NACHTSHEIM  
 2                   MR. SACCHET: Sure.  
 3                   THE WITNESS: Yes.  
 4                   (Whereupon, Exhibit 26 was  
 5                   marked for identification.)  
 6                   MR. SACCHET: I believe it was  
 7                   marked, was it?  
 8                   THE WITNESS: Yeah, this is  
 9                   Exhibit 26.  
 10                  BY MR. SACCHET:  
 11                  Q. So does the website address at the bottom  
 12                  left-hand corner of Exhibit 26 --  
 13                  A. Oh, does it match, I see what you're saying.  
 14                  Q. -- match the --  
 15                  A. Yes, it does. It does.  
 16                  Q. If you could take a moment to just scan the  
 17                  three odd pages of the article.  
 18                  A. (Reviews document.)  
 19                  MS. GARCIA: Is there a question?  
 20                  MR. SACCHET: There's not one  
 21                  pending.  
 22                  MS. GARCIA: Okay. Thank you.  
 23                  THE WITNESS: (Reviews document.)  
 24                  Okay.  
 25                  BY MR. SACCHET:

Page 324

1                   NACHTSHEIM  
 2                  review where that shows up. Is that --  
 3                  MR. SACCHET: That's --  
 4                  THE WITNESS: That's what --  
 5                  MR. SACCHET: Exhibit --  
 6                  THE WITNESS: Oh, yes, "Hard to  
 7                  disagree with the last quote" --  
 8                  MR. SACCHET: The last quote.  
 9                  THE WITNESS: -- "where the guy  
 10                 said the data are compelling, but they don't  
 11                 prove a link to infections in practice and a  
 12                 clinical trial would be needed to do that?"  
 13                  MR. SACCHET: Yup.  
 14                  BY MR. SACCHET:  
 15                  Q. And the last quote also says that, "Proving  
 16                 such a link might be impossible, because it  
 17                 would require mounting a huge clinical  
 18                 study," correct?  
 19                  A. Correct.  
 20                  Q. In the absence of a clinical study, is the  
 21                 next best evidence observational data?  
 22                  MS. GARCIA: Object to the form of  
 23                 the question.  
 24                  THE WITNESS: Yes. In the absence  
 25                 of a -- of an experimental or a clinical

Page 323

1                   NACHTSHEIM  
 2                  Q. Just a few quick questions about the article.  
 3                  Did you find any reference to the  
 4                  McGovern study or the McGovern data in the  
 5                  article?  
 6                  A. I did not.  
 7                  Q. This study was -- or this article from the  
 8                  New York Times was in fact published  
 9                  approximately 11 months before the McGovern  
 10                 article was published, wasn't it?  
 11                  A. Yes, it was.  
 12                  Q. The only data mentioned in the article are  
 13                  those presented to the ECRI Institute that  
 14                  you can find at the top of the last full text  
 15                  page, correct?  
 16                  A. Yes.  
 17                  Q. And at the bottom of the article is  
 18                  presumably what you and Mr. Albrecht were  
 19                  referring to in your correspondence marked in  
 20                  Exhibit 19 in which you say something to the  
 21                  effect of, "His statement is hard to argue  
 22                  with," correct?  
 23                  MS. GARCIA: Object to the form of  
 24                 the question.  
 25                  THE WITNESS: I just wanted to

Page 325

1                   NACHTSHEIM  
 2                  study, it's the -- the only evidence you  
 3                  would have would be observational data.  
 4                  BY MR. SACCHET:  
 5                  Q. And you agreed with the statement made by  
 6                 Dr. Jeffrey Gumprecht that it would be  
 7                 impossible to mount a huge clinical study,  
 8                 correct?  
 9                  MS. GARCIA: Object to the form of  
 10                 the question.  
 11                  THE WITNESS: I -- I really -- I  
 12                 really don't know for sure that it would be  
 13                 impossible. I don't know what -- first of  
 14                 all, I think it's possible. I don't know  
 15                 what it would cost. I don't know -- I'd have  
 16                 to think through how that kind of study would  
 17                 be designed and -- and -- and the logistical  
 18                 problems that might present themselves. I  
 19                 don't see any impossibility.  
 20                  MR. SACCHET: Okay.  
 21                  BY MR. SACCHET:  
 22                  Q. Assuming a randomized control trial could not  
 23                 be conducted, observational data would be the  
 24                 next best alternative?  
 25                  MS. GARCIA: Object to the form of

<p style="text-align: right;">Page 326</p> <p>1                    NACHTSHEIM      2        the question.      3        THE WITNESS: That would be the      4        next best alternative.      5        BY MR. SACCHET:      6        Q. Why is that?      7        A. Here what we're doing with the -- with the      8        randomized -- with a clinical trial is that      9        we're going to actually put both -- both      10      types of blankets in practice and we can look      11      at -- look directly at infection rates that      12      result from the two different conditions, and      13      that's the -- that's the clinical study. If      14      you're looking at -- if you want to know      15      about infections, I think you're limited to      16      looking at observational studies such as --      17      such as the one that we report on.      18      We did -- we did experimental      19      studies on bubbles, but we can't do      20      experimental studies on infections without --      21      without resorting to a clinical trial of some      22      kind.      23      So I think that, yeah, I think you      24      probably -- if you want to look at      25      infections, I think you're -- I think you're</p>	<p style="text-align: right;">Page 327</p> <p>1                    NACHTSHEIM      2        probably limited to observational data.      3        Q. Isn't it true that a well-designed      4        observational study can render results      5        extremely similar to a properly conducted      6        randomized trial --      7        MS. GARCIA: Object --      8        BY MR. SACCHET:      9        Q. -- on the same subject matter?      10      MS. GARCIA: Object to the form of      11      the question.      12      THE WITNESS: I think that can      13      happen, but I don't believe that the level of      14      proof reaches the same -- I don't think that      15      the proof reaches the same level of rigor.      16      There's just always that chance in      17      observational studies that -- I mean, I think      18      there's a greater chance that something -- a      19      confounding factor might be present,      20      something you just hadn't thought of.      21      BY MR. SACCHET:      22      Q. But it is possible that if statistical      23      significance is found based on observational      24      data, that that significance may be      25      replicated in a randomized control trial?</p>
<p style="text-align: right;">Page 328</p> <p>1                    NACHTSHEIM      2        A. Yes.      3        Q. So the observational data that is presented      4        in the McGovern study is certainly valuable,      5        is it not?      6        MS. GARCIA: Object to the form of      7        the question.      8        THE WITNESS: I think it's      9        valuable.      10      BY MR. SACCHET:      11      Q. That's why you published the observational      12      data, correct?      13      A. Yes.      14      Q. You were previously asked about potentially      15      confounding factors with respect to the      16      observational data that was presented in the      17      McGovern study, correct?      18      A. Correct.      19      Q. And some of those potentially confounding      20      factors dealt with infection control      21      measures, correct?      22      A. Correct.      23      Q. If we could turn to page 1540 of Exhibit 4,      24      the McGovern study.      25      A. (Complies.)</p>	<p style="text-align: right;">Page 329</p> <p>1                    NACHTSHEIM      2        Q. I want to make sure that we are on the same      3        page with respect to the change that occurred      4        as to the antibiotic regime. Would you agree      5        that an antibiotic called Gentamycin was      6        applied during the forced-air warming period      7        from July 1st, 2008, to the end of February      8        2009? It's about halfway down the paragraph.      9        A. I see it. From July 2008 to February 2009 a      10      single dose of Gentamicin 4.5 was given at --      11      at induction.      12      Q. Whereas, a combination of Gentamycin and      13      Teicoplanin -- and I'd be surprised if any of      14      us know how to pronounce it, but that's how      15      I'm going to say it -- was applied during the      16      end of the forced-air warming period and      17      throughout the entire conductive fabric      18      warming period, which would namely be      19      March 1st, 2009, until January 2011, correct?      20      MS. GARCIA: Can you please point      21      to where you're reading from?      22      MR. SACCHET: So I am interpreting      23      what's said in this paragraph and based on      24      what's presented in Figure 7 so --      25      MS. GARCIA: Okay. Then I'll</p>

<p style="text-align: center;">Page 330</p> <p>1                    NACHTSHEIM      2 object to the form of the question.      3                    THE WITNESS: I -- I read this --      4                    MR. SACCHET: I can walk through      5 it slower.      6                    THE WITNESS: Well, I read this to      7 say that in March 2009 there was a change to      8 the combination of the two drugs you've      9 pronounced, and I don't believe there were      10 any changes until the end of the study.      11                    MR. SACCHET: Okay.      12 BY MR. SACCHET:      13 Q. So -- so we're clear, there was a period in      14 which Gentamycin was applied to some      15 forced-air warming patients, and then the      16 antibiotic changed to a combination of      17 Gentamycin and Teicoplanin that applied to      18 some forced-air warming patients and all of      19 the conductive fabric warming patients,      20 correct?      21 A. Correct.      22 Q. Assuming the change in antibiotic did not      23 affect infection rates between warming      24 devices, would you still consider the      25 antibiotic a confounding variable?</p>	<p style="text-align: center;">Page 331</p> <p>1                    NACHTSHEIM      2 MS. GARCIA: Object to the form of      3 the question.      4                    THE WITNESS: I'm going to assume      5 that it has -- the change had no effect?      6 BY MR. SACCHET:      7 Q. Yeah, assume that the antibiotic had no      8 effect on the infection rate. Would it still      9 be a confounding variable?      10                    MS. GARCIA: Object to the form of      11 the question.      12                    THE WITNESS: I don't think it      13 would be -- I don't think it would be      14 considered a confounding variable. I'm      15 trying to think of how else it might have an      16 impact, if it's not having an effect. I      17 guess it -- no, I don't think it would be,      18 yeah.      19 BY MR. SACCHET:      20 Q. One way that we could control for the -- let      21 me strike that.      22                    In order to determine whether the      23 antibiotic had an effect on infection rates,      24 we could control for the warming device --      25 A. Yes.</p>
<p style="text-align: center;">Page 332</p> <p>1                    NACHTSHEIM      2 Q. -- and evaluate whether infection rates      3 between the changed antibiotic stayed the      4 same or went up or down --      5 A. Correct.      6 Q. -- with that control device, correct?      7 A. (Nods head.)      8                    MS. GARCIA: I'm going to object      9 to the form of the question.      10 BY MR. SACCHET:      11 Q. Did you understand it?      12 A. Yes.      13 Q. If infection rates between the two groups      14 were similar, that would tend to show that      15 the antibiotic was not a confounding factor?      16 A. Correct.      17                    MS. GARCIA: Object to the form of      18 the question.      19 BY MR. SACCHET:      20 Q. Assume that Mr. Albrecht, who you previously      21 mentioned was an expert in statistics and you      22 had full confidence in his ability to analyze      23 data presented in this article, informed you      24 that he found a 2.8 percent infection rate in      25 those who received Gentamycin, a single drug,</p>	<p style="text-align: center;">Page 333</p> <p>1                    NACHTSHEIM      2 but 3.1 percent of patients who received the      3 combination of antibiotics, but also      4 forced-air warming patients, with a nearly      5 identical infection rate, would you determine      6 that the antibiotic was a confounding factor?      7                    MS. GARCIA: Object to the form of      8 the question.      9                    THE WITNESS: That would be strong      10 evidence that it was not a confounding      11 factor.      12                    MR. SACCHET: Let's mark this.      13                    (Whereupon, Exhibit 27 was      14 marked for identification.)      15 BY MR. SACCHET:      16 Q. So just to be clear, if we look at this table      17 that's presented here, we can see in the      18 first line it presents antibiotic protocol 1      19 versus 2 for FAW, does it not?      20 A. It does.      21 Q. Assume that protocol 1 is the singular      22 antibiotic, i.e. Gentamycin, and that      23 protocol 2 is the combination of Gentamycin      24 and Teicoplanin.      25 A. Uh-huh. Yes.</p>

<p style="text-align: center;">Page 334</p> <p>1                   <b>NACHTSHEIM</b></p> <p>2     Q. In this particular analysis, forced-air 3       warming is held constant, correct?</p> <p>4     A. Correct.</p> <p>5     Q. And for forced air, protocol 1, the percent 6       of patients developing infection was 2.8?</p> <p>7     A. Correct.</p> <p>8     Q. And for forced air, protocol 2, involving 9       patients who received both Gentamycin and 10      Teicoplanin, the infection rate was 3.1, 11      correct?</p> <p>12     A. Correct.</p> <p>13     Q. And the p-value was 0.839, correct?</p> <p>14     A. That's what's reported here.</p> <p>15     Q. That's what's reported here. We could 16      conclude, based on this data set of these 17      numbers, that when the patient-warming device 18      is held constant, that the change in 19      antibiotic had no effect on infection rates, 20      correct?</p> <p>21                  MS. GARCIA: Object to the form of 22      the question.</p> <p>23                  THE WITNESS: Assuming there's 24      sufficient power in those sample sizes, 25      although they look fairly large to me, yes.</p>	<p style="text-align: center;">Page 335</p> <p>1                   <b>NACHTSHEIM</b></p> <p>2     BY MR. SACCHET:</p> <p>3     Q. The patient population for forced-air 4       protocol 1 was 389 patients, correct?</p> <p>5     A. Correct.</p> <p>6     Q. And the patient population for those 7       receiving the combination was 678, correct?</p> <p>8     A. Correct.</p> <p>9     Q. Those are fairly large patient populations, 10      correct?</p> <p>11     A. Correct.</p> <p>12                  MS. GARCIA: Object to the form of 13      the question.</p> <p>14                  BY MR. SACCHET:</p> <p>15     Q. Another way to determine whether the 16      antibiotic was a confounding variable would 17      be to control the antibiotic, but evaluate 18      different infection rates between different 19      forced-air -- or different warming devices, 20      correct?</p> <p>21     A. Yes.</p> <p>22                  MS. GARCIA: Object to the form of 23      that question also.</p> <p>24                  BY MR. SACCHET:</p> <p>25     Q. And if the infection rates were still higher</p>
<p style="text-align: center;">Page 336</p> <p>1                   <b>NACHTSHEIM</b></p> <p>2     among those who received forced-air warming 3       compared to those who received conductive 4       fabric warming, that would tend to show the 5       antibiotic did not substantially affect 6       infection rates, correct?</p> <p>7     A. Correct.</p> <p>8                  MS. GARCIA: Object to the form of 9      the question.</p> <p>10                 BY MR. SACCHET:</p> <p>11     Q. And if that's true, the change in antibiotic 12      would also not be a confounding factor, 13      correct?</p> <p>14     A. Correct.</p> <p>15                 MS. GARCIA: Object to the form of 16      the question.</p> <p>17                 BY MR. SACCHET:</p> <p>18     Q. If I could --</p> <p>19                 MR. SACCHET: Could I ask your 20      basis for the objection?</p> <p>21                 MS. GARCIA: I'm sorry?</p> <p>22                 MR. SACCHET: Could I ask your 23      basis for the objection on form?</p> <p>24                 MS. GARCIA: Yes. You keep using 25      the word, "determine," and you keep using the</p>	<p style="text-align: center;">Page 337</p> <p>1                   <b>NACHTSHEIM</b></p> <p>2     word, "show," and you keep using the word, 3       "establish," and I'm objecting to the form of 4       the question based on those terms.</p> <p>5                  MR. SACCHET: That's not going to 6      pass muster in the court.</p> <p>7                 BY MR. SACCHET:</p> <p>8     Q. As to the hypothetical I just presented, if 9      you could turn your attention to the second 10     line of the table.</p> <p>11                 MS. GARCIA: I'm sorry, to just be 12      complete with my form objection, it's also an 13      incomplete hypothetical.</p> <p>14                 MR. SACCHET: Fair enough.</p> <p>15                 BY MR. SACCHET:</p> <p>16     Q. Antibiotic protocol 2 involved a combination 17      have Gentamycin and Teicoplanin, correct?</p> <p>18                 MS. GARCIA: Object to 19      foundation --</p> <p>20                 BY MR. SACCHET:</p> <p>21     Q. -- for the sake of --</p> <p>22                 A. Yes.</p> <p>23                 MS. GARCIA: Excuse me. Object to 24      foundation for that.</p> <p>25                 BY MR. SACCHET:</p>

<p style="text-align: right;">Page 338</p> <p style="text-align: center;"><b>NACHTSHEIM</b></p> <p>Q. And the data here shows that 3.1 percent of patients who received forced-air warming in the combination antibiotic developed joint infections, correct?</p> <p>A. Correct.</p> <p>Q. Whereas, .9 percent of patients who received conductive fabric warming and the combination of antibiotics developed joint infections, correct?</p> <p>A. Correct.</p> <p>Q. By holding the antibiotic constant and discontinuing the use of forced-air warming, that resulted in a 71 percent decrease in joint infections, did it not?</p> <p>MS. GARCIA: Object to the form of the question.</p> <p>THE WITNESS: Yes, it did.</p> <p>BY MR. SACCHET:</p> <p>Q. That essentially matches the 73 percent decrease in infections that was noted in the McGovern article itself, does it not?</p> <p>A. Correct.</p> <p>MS. GARCIA: Object to the form of the question.</p>	<p style="text-align: right;">Page 341</p> <p style="text-align: center;"><b>NACHTSHEIM</b></p> <p>BY MR. SACCHET:</p> <p>Q. And based on the p-value of .0008, which is far less than .05, you would determine that difference to be statistically significant, would you not?</p> <p>A. I would.</p> <p>Q. So whether we control for the device or control for the antibiotic, based on this data set in Exhibit 27, would you determine that the antibiotic was not a confounding factor?</p> <p>MS. GARCIA: Object to the form of the question, it's a lack of foundation, it's an incomplete hypothetical.</p> <p>THE WITNESS: This data certainly supports that hypothesis.</p> <p>BY MR. SACCHET:</p> <p>Q. And if it were not a confounding factor, would there be any reason to deselect patients from the population of 1,437 accounted for in the McGovern study in order to exclude those who received a single antibiotic?</p> <p>A. No.</p>
<p style="text-align: right;">Page 340</p> <p style="text-align: center;"><b>NACHTSHEIM</b></p> <p>MS. GARCIA: Object to the form of the question.</p> <p>BY MR. SACCHET:</p> <p>Q. And if we were to do that and reduce the population, let's say, from the 1,473, or 37, I've forgotten which number it is, down to a number of let's say 500 patients, there could be concern about the powering of that population?</p> <p>A. There could. There could be.</p> <p>Q. Another confounding factor that was discussed this afternoon was a change in the thromboprophylaxis protocol, correct?</p> <p>A. Yes. Can -- can you just remind me where that --</p> <p>Q. Yeah, if we could turn to page 1540.</p> <p>A. (Complies.)</p> <p>Q. If you look at the bottom of the first full paragraph in the left-hand column, it states the thromboprophylaxis regimen from July 2008 to the end of July 2009 was Tinzaparin.</p> <p>A. Uh-huh.</p> <p>Q. Then it says from August 2009 to February</p>	<p style="text-align: right;">Page 341</p> <p style="text-align: center;"><b>NACHTSHEIM</b></p> <p>2010, Rivaroxaban, which I'll represent is otherwise known as Xarelto, was provided from day one, but in February 2010 to the end of this study, patients were reverted to Tinzaparin, correct?</p> <p>A. Yes.</p> <p>Q. Assuming the change in the prophylaxis did not affect infection rates during the time of this study, i.e., Exhibit 4, would you still consider it a confounding variable?</p> <p>A. No.</p> <p>MS. GARCIA: Object to the form of the question. (Whereupon, Exhibit 28 was marked for identification.)</p> <p>MS. GARCIA: What number are we on?</p> <p>MR. SACCHET: Twenty-eight, I believe.</p> <p>THE COURT REPORTER: Correct.</p> <p>MS. GARCIA: Thank you.</p> <p>BY MR. SACCHET:</p> <p>Q. Have you seen this document before, Professor?</p>

<p style="text-align: center;">Page 342</p> <p>1                    NACHTSHEIM      2        A. No, I have not.      3        Q. Was this document produced with the set of      4                    documents that you provided to 3M in response      5                    to the subpoena?      6        A. No.      7        Q. Does the bottom right-hand label of this      8                    document bear a Bates number of Nachtsheim --      9        A. It does.      10      Q. -- space 0000451?      11      A. It must have been attached to one of my      12                  e-mails. I -- I -- I don't remember seeing      13                  the document.      14      Q. Since you don't remember receiving or reading      15                  the document, let's go through it.      16      A. Okay.      17      Q. If you'd turn to the second page of text that      18                  bears the heading, "Introduction"; do you see      19                  that?      20      A. I do.      21      Q. Do you see the last paragraph at the bottom      22                  of that page?      23      A. "This multicenter study"?     24      Q. Correct. I'll read it out loud and you just      25                  confirm that we're on the same page. "This</p>	<p style="text-align: center;">Page 343</p> <p>1                    NACHTSHEIM      2                    multicenter study based on prospectively      3                    collected national data aims to evaluate the      4                    surgically relevant complications of using      5                    either Rivaroxaban, or LMWH," which I'll      6                    represent means low molecular weight      7                    heparins, "as thromboprophylaxis, including      8                    wound complications, readmission and return      9                    to theater for deep infection, in addition to      10                  the incidents of major bleeds and EVT,"      11                  correct?      12      A. Correct.      13      Q. Based on that statement, do you agree that at      14                  least two or three outcomes were measured,      15                  one being wound complications, another being      16                  return to theater for deep infection, and      17                  another being major bleeds?      18      A. I agree.      19                  MS. GARCIA: I object to lack of      20                  foundation.      21                  BY MR. SACCHET:      22      Q. If you could turn to the next page under,      23                  "Methods," in the third paragraph it states,      24                  "The primary outcome measure was wound      25                  complications," parens, "Including hematoma,</p>
<p style="text-align: center;">Page 344</p> <p>1                    NACHTSHEIM      2                    superficial wound infection and deep      3                    infection requiring return to theater, RTT,      4                    within 30 days of procedure"; do you see      5                    that?      6      A. I do.      7      Q. And you see the designation that RTT involves      8                  a deep infection requiring a return to      9                  theater, correct?      10     A. Correct.      11     Q. Which is one of the independent variables      12                  that was mentioned in the prior paragraph      13                  that we read, correct?      14                  MS. GARCIA: Object to the form of      15                  the question.      16                  THE WITNESS: Correct. I think      17                  dependent variables.      18                  MR. SACCHET: Okay. Noted.      19                  BY MR. SACCHET:      20      Q. If we can now turn to the next page under,      21                  "Results," do you see that heading?      22      A. Yes, 456.      23      Q. It says, "During the study period, 2,762      24                  patients received Rivaroxaban, and 10,361      25                  received LMWH. Patient demographics are</p>	<p style="text-align: center;">Page 345</p> <p>1                    NACHTSHEIM      2                    shown in table 1. There were significantly      3                    fewer wound complications in the LMWH group, "      4                    parens, "2.81 percent versus 2.85 percent, OR      5                    equals .72, 95 percent confidence intervals      6                    between 0.58 to 0.90 with a p-value of .005.      7                    However, rates of RTT for infected wound      8                    washout were not significantly different."      9                    Do you see that?      10     A. I do.      11     Q. Assuming the truth of this study in what we      12                  just read, would you agree that Rivaroxaban,      13                  otherwise known as Xarelto, increased wound      14                  complications compared to low weight      15                  molecular heparins like Tinzaparin?      16                  MS. GARCIA: Object to the form of      17                  the question, to an incomplete hypothetical      18                  and to a lack of foundation for this witness      19                  to opine about the meaning of this article.      20                  THE WITNESS: It says there were      21                  significantly fewer wound complications in      22                  the LMH -- LMWH group. Is that what you're      23                  referring to?      24                  BY MR. SACCHET:      25                  Q. That's what I'm referring to. And the</p>

<p style="text-align: center;">Page 346</p> <p>1                    NACHTSHEIM      2        p-value was a statistically significant      3        value, correct?      4        A. Yes, correct.      5        Q. So there were fewer wound complications as a      6        result of the use of a low weight molecular      7        heparin --      8        A. Correct.      9        Q. -- compared to Rivaroxaban, correct?      10      A. Yeah, correct.      11      MS. GARCIA: Object to the form of      12      the question.      13      BY MR. SACCHET:      14      Q. However, the study notes that rates for RTT,      15      which we established to be a return to      16      theater for --      17      A. Uh-huh.      18      Q. -- infections, were not significantly      19      different; do you see that?      20      A. Correct. Yes, I do.      21      Q. Assuming the truth -- well, let me back up.      22      Would you also agree that the      23      McGovern study, Exhibit --      24      MS. GARCIA: Four.      25      BY MR. SACCHET:</p>	<p style="text-align: center;">Page 347</p> <p>1                    NACHTSHEIM      2        Q. -- 4, evaluated joint infections?      3        A. Yes.      4        Q. It did not evaluate wound complications, did      5        it?      6        A. Correct, it did not.      7        Q. Assuming the truth of this study, would you      8        ultimately agree that the change in protocol      9        from Tinzaparin, which is an LMWH, to      10      Xarelto, otherwise known as Rivaroxaban, and      11      then back to Tinzaparin, did not      12      significantly affect the infection rate?      13      MS. GARCIA: Object to the form of      14      the question, to lack of foundation, and it's      15      an incomplete hypothetical.      16      THE WITNESS: Assuming the study      17      was carefully done and generalizable, yes.      18      BY MR. SACCHET:      19      Q. And assuming the study was well done and      20      generalizable, would you agree that the      21      change in thromboprophylaxis noted in the      22      McGovern study, Exhibit 4, did not confound      23      the infection rates?      24      MS. GARCIA: Object to the form of      25      the question.</p>
<p style="text-align: center;">Page 348</p> <p>1                    NACHTSHEIM      2        THE WITNESS: Assuming -- yes.      3      BY MR. SACCHET:      4      Q. And would you also conclude that, assuming      5      the truth of this study, it would be improper      6      to deselect all of the patients who received      7      Xarelto, otherwise known as Rivaroxaban, from      8      the patient population if the      9      thromboprophylaxis was not a confounding      10     variable?      11     MS. GARCIA: Object to the form of      12     the question.      13     THE WITNESS: It doesn't seem      14     justified in -- on the basis of these      15     results.      16     BY MR. SACCHET:      17     Q. And, in fact, when the coauthors of the      18     McGovern study were in the process of      19     publication, are you aware that at numerous      20     times they sought to collect additional data      21     in support of the study?      22     A. I was not aware of that. I knew that -- I      23     knew that they sought to run this study out      24     in time.      25     Q. Are you aware that when Mr. Albrecht and</p>	<p style="text-align: center;">Page 349</p> <p>1                    NACHTSHEIM      2        Dr. Reed collected additional data that went      3        beyond January 2011 in the conductive fabric      4        warming population, that the data still      5        showed a significant decrease in infections      6        when conductive fabric warming was used?      7        A. I'm aware of that.      8        Q. Assuming that --      9        MS. GARCIA: Can we take a break      10      shortly?      11      MR. SACCHET: Yeah, give me two      12      minutes.      13      BY MR. SACCHET:      14      Q. Assuming that neither the antibiotic nor the      15      thromboprophylaxis protocol required control      16      because they were not confounding factors as      17      we discussed, you would be confident in the      18      results of the observational study presented      19      in the McGovern data?      20      MS. GARCIA: Object to the form of      21      the question.      22      THE WITNESS: I'm confident that      23      those weren't confounding factors, that those      24      studies are well done. It doesn't rule out      25      the potential for other confounding factors.</p>

<p style="text-align: right;">Page 350</p> <p>1                   NACHTSHEIM 2                   MR. SACCHET: Fair enough. 3 BY MR. SACCHET: 4 Q. And you continue to stand by the results of 5                   the observational studies -- 6 A. Yes. 7 Q. -- in the McGovern publication? 8 A. I do. 9                   MR. SACCHET: Let's take a break. 10                  THE VIDEOGRAPHER: We're going off 11                  the record at 5:07 p.m. 12                  (Whereupon, a brief recess 13                  was taken.) 14                  THE VIDEOGRAPHER: This is video 15                  number 6 in the deposition of Christopher 16                  Nachtsheim. Today is November 29th, 2016. 17                  We're going back on the record at 5:18 p.m. 18 BY MR. SACCHET: 19 Q. Professor Nachtsheim, if we could turn to 20                  Exhibit 5, which is the Belani study. 21 A. I have it. 22 Q. Great. And as to this study, your role was 23                  to exclusively review the statistical portion 24                  of this study, correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 351</p> <p>1                   NACHTSHEIM 2                   Q. You had no involvement in the setup of the 3                   experiment? 4 A. I did not. 5                   Q. You had no role in the execution of the 6                   physical experiment? 7 A. I did not. 8                   Q. You had seen, whether by video or in person, 9                   disruption of laminar flow caused by the 10                  Bair Hugger before, correct? 11 A. I had, yes. 12                  MS. GARCIA: I'm sorry, can I hear 13                  that question again? I was thinking and I 14                  did not hear the question. 15                  MR. SACCHET: Can you -- do you 16                  mind repeating it. 17                  (Whereupon, the last question 18                  was read by the court reporter.) 19                  MS. GARCIA: Object to the form of 20                  the question, asked and answered. 21 BY MR. SACCHET: 22 Q. So you were familiar with the possibility, 23                  based on your personal experience, that the 24                  Bair Hugger could disrupt laminar airflow, 25                  correct?</p>
<p style="text-align: right;">Page 352</p> <p>1                   NACHTSHEIM 2                   MS. GARCIA: Object to the form of 3                   the question, misstates the record and lack 4                   of foundation. 5                   THE WITNESS: Correct. 6 BY MR. SACCHET: 7 Q. If we could turn to the third page of the 8                  study. 9 A. (Complies.) 408? 10 Q. Yes. Do you see the header entitled, 11                  "Statistical Analysis"? 12 A. I do. 13 Q. And it reads, "A Poisson regression model for 14                  overdispersed data was fit having the sum of 15                  bubble counts for each experimental run," 16                  paren, "ten pictures," end parens, "as the 17                  response, and the factors identified in the 18                  experimental design as predictors plus an 19                  interaction term." Do you see that? 20 A. I do, yes. 21 Q. Did you determine that a Poisson regression 22                  was the most appropriate statistical model to 23                  employ because you were dealing with counts 24                  data -- or data counts? 25 A. Yes.</p>	<p style="text-align: right;">Page 353</p> <p>1                   NACHTSHEIM 2                   MS. GARCIA: Object to the form of 3                   the question, previously asked and answered. 4 BY MR. SACCHET: 5 Q. And that Poisson regression was a better 6                  model to use than, let's say, an ANOVA model? 7                   MS. GARCIA: Object to the form of 8                  the question, previously asked and answered. 9                   THE WITNESS: Yes. 10 BY MR. SACCHET: 11 Q. And if we could just turn our attention one 12                  paragraph above that, it says, "For the 13                  experimental design, a replicated and equals 14                  to 2 by 3 full factorial design was used to 15                  assess changes in bubble counts over the 16                  surgical site," correct? 17 A. Correct. 18 Q. And what were the factors? 19 A. So the first factor is the anesthesia screen, 20                  low grade/high grade, those are the two 21                  levels, and then there were three 22                  patient-warming devices, conductive fabric, 23                  forced-air or no warming device, and that 24                  would -- that was considered a control. 25 Q. Does Figure 3, directly above that paragraph,</p>